REMARKS

Claims 1-12 are pending in the instant application. Claims 2-6 and 8-12 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1 and 7 have been rejected. Claim 1 has been amended. Claim 7 has been canceled in light of the amendments to claim 1. Support for the amendments to claim 1 is provided in the specification at page 3, line 21 through page 4, line 3, page 7, lines 2-21 and claim 7, now canceled. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed June 18, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled nonelected claims 2-6 and 8-12, without prejudice. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Information Disclosure Statements

The Examiner suggests that the references provided with the Information Disclosure Statements filed December 17, 2001, June 13,

2002 and July 31, 2002 are missing from the file. Therefore, in accordance with the Examiner's invitation to Applicants to resubmit the references, and a telephone discussion on May 9, 2003 with the Examiner regarding the form in which these reference could be submitted, Applicants are providing herewith a computer-readable format (CD-ROM) containing substitute copies of all patents and published patent applications cited in these Information Disclosure Statements. As discussed with the Examiner on May 9, 2003, if the references cannot be viewed in this form, Applicants will then provide replacement paper copies of the missing references. Applicants are also providing herewith substitute papers copies of the literature references cited in these Information Disclosure Statements.

III. Objection to Claims 1 and 7

Claim 1 has been objected to as encompassing non-elected inventions. Claim 1 has also been objected to for use of the abbreviation "CSG". In addition, claim 1 has also been objected to for the language "normal" human control as the Examiner suggests that it is not clear what constitutes "normal". Claim 7 has also been objected to as depending on non-elected claims and encompassing non-elected inventions.

Accordingly, in an earnest effort to advance the prosecution

of this case, Applicants have amended claim 1 to be drawn to the elected invention. The abbreviation CSG has also been deleted from the claim.

Claim 7 has been canceled in light of the amendments to claim 1.

With respect to the Examiner's suggestion that the term "normal" is not clear", Applicants respectfully disagree. Clarity or definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in that pertinent art at the time the invention was made. See MPEP § 2173. The content of the particular application disclosure contains a definition for the phrase normal human control. See specifically, page 9, lines 14-19 wherein it is taught "normal human control as used herein includes a human patient without cancer and/or non cancerous samples from the patient; in the methods for diagnosing or monitoring for metastasis, normal human control may preferably also include samples from a human patient that is determined by reliable methods to have prostate cancer which has not metastasized". Thus, what

constitutes a "normal human control" as set forth in the claims is clear when read in light of the teachings of the specification.

Withdrawal of these objections to the claims is respectfully requested in light of amendments to the claims and the above remarks.

IV. Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph - Written Description

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that the specification does not contain a written description of the invention in such full, clear, concise and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing. The Examiner has acknowledged claims to a method for detecting the presence of prostate cancer comprising determining the mRNA level of a polynucleotide sequence comprising SEQ ID NO: 7 or 8 to meet the written description provisions of 35 U.S.C. § 112, first paragraph. However, the Examiner suggests that the claims, as written, encompass polynucleotides which vary substantially in length and also in nucleotide composition since the specification discloses CSG to mean polynucleotides capable of hybridizing under stringent conditions to the antisense sequence of SEQ ID NO: 7 or 8.

Further, the Examiner suggests that the claims encompass the structure of genes not disclosed in the specification since CSG is also defined as a gene comprising SEQ ID NO: 7 or 8.

Applicants respectfully traverse this rejection.

In accordance with MPEP § 2163, an adequate written description of the invention may be shown by any description of sufficient, relevant and identifying characteristics so long as a person skilled in the art would recognize that the inventor has possession of the claimed invention. What is conventional or well known to one of ordinary skill in that art need not be disclosed in detail. See MPEP § 2163 and Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d at 1384, 231 USPQ at 94. Thus, in accordance in with MPEP § 2163, if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description is met. Also see Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116; Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972). Once a polynucleotide sequence such as SEQ ID NO:7 or 8 has been identified, means for assessing whether another polynucleotide hybridizes under stringent conditions to these sequences can be performed routinely in accordance with

methods such as set forth in standard reference texts such as Sambrook et al. 1989 (Molecular Cloning, A Laboratory Manual, 2nd Edition, Cold Spring Harbor Press, Cold Spring Harbor). Accordingly, further details regarding polynucleotides which hybridize under stringent conditions with SEQ ID NO:7 or 8 need not be explicitly described in the specification for adequate written description.

Applicants believe that any additional sequences of a gene comprising SEQ ID NO: 7 or 8 can also be identified routinely once the polynucleotide of SEQ ID NO: 7 or 8 has been identified. Accordingly, further details relating to genes comprising polynucleotides of SEQ ID NO:7 or 8 need not be explicitly described in the specification for adequate written description.

However, in an earnest effort to advance the prosecution of this case, but without conceding in anyway to the Examiner's suggestions, Applicants have amended the claims by replacing the term "CSG" with the phrase --polynucleotide comprising SEQ ID NO: 7 or 8 or a protein expressed thereby--. Support for this amendment can be found throughout the specification and in particular in claim 7, now canceled, and at page 3, line 21 through page 4, line 3, and page 7, lines 2-21. Thus, the instant application clearly provides sufficient, relevant and identifying

characteristics in the specification so that a person skilled in the art would recognize that the inventor has possession of the invention as now claimed.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

V. Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph, - Lack of Enablement

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that the specification does not enable any person skilled in the art to which is pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. The Examiner has acknowledged the specification to be enabling for a method for detecting the presence of prostate cancer comprising determining the mRNA levels or SEQ ID NO: 7 or 8 in prostate tissues using probes SEQ ID NO: 27 and 28. However, the Examiner suggests that the specification does not reasonably provide enablement for a method for detecting the presence of prostate cancer, comprising determining the level of "CSG". In particular, the Examiner suggests that the specification is not enabling for polynucleotides that hybridize to a polynucleotide of SEQ ID NO:7 or 8 or genes comprising SEQ ID NO: 7 or 8.

Applicants respectfully traverse this rejection since identify hybridizing polynucleotides as well a genes containing a polynucleotide sequence can be performed routinely by those skilled in the art upon disclosure of a selected polynucleotide sequence such as SEQ ID NO: 7 or 8.

However, in an earnest effort to advance the prosecution of this case, but without conceding in anyway to the Examiner's suggestions, Applicants have amended the claims by replacing the term "CSG" with the phrase --polynucleotide comprising SEQ ID NO: 7 or 8 or a protein expressed thereby--. Support for this amendment can be found throughout the specification and in particular in claim 7, now canceled, and at page 3, line 21 through page 4, line 3, and page 7, lines 2-21. The instant specification, which teaches the full length polynucleotide sequences for SEQ ID NO:7 and 8 and presents data demonstrative of their use as markers in prostate cancer is clearly enabling for the invention as now claimed.

Claims 1 and 7 have also been rejected under 35 U.S.C. § 112, first paragraph, because the Examiner suggests that the specification is not enabling for a method of detecting the presence of prostate cancer comprising determining the mRNA levels of a CSG or SEQ ID NO: 7 or 8, in "any cell or tissue" using "any

probe", but rather is enabling only for a method of detecting mRNA levels of SEQ ID NO: 7 or 8 in prostate tissue using probes SEQ ID NO: 27 and 28. The Examiner suggests that metastatic cells in other tissues may not express SEQ ID NO:7 or 8. Further, the Examiner suggests that other probes may detect interfering sequences such as epitheliasin expressed in prostate and 99.6% similar to SEQ ID NO: 8 from nucleotide 22 to 3222.

Applicants respectfully traverse this rejection.

In accordance with MPEP §2164.04, a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support. In accordance with MPEP § 2164, the invention that one skilled in the art must be enabled to make and use is that defined by the claims.

The pending claim of the instant application is drawn to a method for diagnosing the presence of prostate cancer by determining levels of a polynucleotide comprising SEQ ID NO: 7 or 8 or a protein expressed thereby in cells, tissues or bodily fluids

in a patient and comparing these determined levels to a normal human control. Accordingly, references relating to altered expression in metastatic cancers as cited by the Examiner are not relevant to predictability of the present invention drawn to diagnosing the presence of prostate cancer.

Further, the pending claim specifies that change in the determined levels of the polynucleotide comprising SEQ ID NO: 7 or 8 or a protein expressed are measured by comparison to levels in a normal human control. Accordingly, the fact that there may be a similar sequence such as epitheliasin expressed in normal prostate tissue is irrelevant to this diagnostic method since all changes in a patient in this diagnostic method are determined by comparison to normal human controls. Thus, any expression of an interfering sequence will be accounted for in the normal control sample as well and will not interfere with measurement of a change in levels of SEQ ID NO:7 or 8 or a protein encoded thereby.

Accordingly, the Examiner has failed to provide reasonable basis to doubt the objective truth of the statements contained therein which must be relied upon for enabling support. For example, at page 18, lines 11-14, the specification makes clear that at the time of filing this application it was well known by those skilled in the art how to design primers and probes specific

to each target gene to detect said gene. Thus, limiting the claims to exemplary probes taught in the instant application is not required to enable the instant claimed invention. See MPEP 2164.01. Similarly, at page 13, lines 27-35, various cells, bodily fluids and/or tissues upon which this diagnostic assay an be carried out are taught. Thus, in accordance with MPEP §2164.01, limiting the claims to prostate tissue is also not required.

Thus, since the instant specification contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented and no reasonable basis has been provided to doubt the objective truth of these statements, the instant specification is in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph. Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

VI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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